#### REMARKS

# **The Amendments**

Claim 1 is amended to recite the properties of the compounds of formula I in the body of the claim; see, e.g., page 6, para. 0017, in the specification for support. Additional dependent claims are added.

The amendments do not narrow the scope of the claims and/or were not made for reasons related to patentability. The amendments should not be interpreted as acquiescence to any objection or rejection made in this application.

Applicants reserve the right to file one or more continuing and/or divisional applications directed to any subject matter disclosed in the application which has been canceled by any of the above amendments.

## **The Restriction Requirement**

Since prosecution has been re-opened, applicants re-assert their traversal of the restriction requirement, particularly the restriction of claims 12 and 13 from the elected claims. The basis previously alleged for restriction of claims 12 and 13 is not relevant to supporting restriction. The fact that the methods for preparing the compositions are merely a mixing of the components together does not support a restriction requirement. Applicants do not dispute that mixing, in general, was well known in the art. But the claims require mixing to provide a novel composition, which was not known in the art. The knowledge of mixing, in general, does not support either that (1) the process can be used to make other materially different products or (2) the product can be made by a materially different process, for the reasons previously set forth. Mixing of different components for making a materially different product is not using applicants' claimed process for such. It is further noted that claim 13 is more than merely mixing, i.e., it requires reactions for making the claim 1 compound. Thus, the previous reasoning in the Office Action does not support restricting claims 12 and 13. Thus, the restriction of these claims should be withdrawn.

Further, as to the method of use claims 14-17, it is urged that, such claims should be rejoined into the application if the general composition claim 1 is found allowable. The reasoning of <u>In re Ochiai</u>, 37 USPQ2d 1127 (Fed. Cir. 1995); and <u>In re Brouwer</u>, 37 USPQ2d 1663 (Fed. Cir. 1996); and the Commissioner's notice thereon dated February 28, 1996,

printed in 1184 OG 86; applies clearly to this application. Therein, it was stated that non-elected process claims which depend from or otherwise include the limitations of allowed product claims will be rejoined and included in the examination of the application upon allowance of the product claims. The reasoning for this is that if the composition is found novel and nonobvious, it is evident that the method for mixing the components to obtain the composition or reacting methods for making the formula I component would necessarily also be novel and nonobvious, i.e., if the composition is novel and nonobvious, there is no motivation to one of ordinary skill in the art to select to make such a composition for mixing.

# The Rejection under 35 U.S.C. §102

The rejection of claims 1-9 and 18 under 35 U.S.C. §102, as being anticipated by Rosenbloom (US Pat. No. 6,753,325), is respectfully traversed.

Rosenbloom is directed to a composition for treating radiation dermatitis which comprises an active compound which regulates cell differentiation and/or proliferation, e.g., a Vitamin D compound, and an anti-oxidant. The composition may optionally also include a flavonoid or other ingredients. The anti-oxidants disclosed by Rosenbloom are exemplified at col. 4, lines 54-60. The optional flavonoids are exemplified at col. 6, lines 12-47.

Rosenbloom is deficient in providing a specific disclosure of an embodiment according to the instant claims in several aspects.

First, Rosenbloom provides no specific disclosure of a composition containing a compound according to applicants' formula I. The Office Action points to the disclosure of 6-hydroxy-luteolin at col. 6, line 17. However, this disclosure only lists this compound in a long list – i.e. 96 compounds – of possible flavonoids which could optionally be used. There is no specific disclosure of a composition which contains such a compound. It is merely included within the long generic list of flavonoid compounds. The reference provides no specific embodiment or specific evidence to suggest that the reference inventors were in possession of a composition containing this compound. A mere broad generic disclosure without any specific direction as to the specific element necessary to provide anticipation is not an anticipatory disclosure. In other words, such a broad generic disclosure does not "describe" an embodiment therein in accordance with 35 U.S.C. §102. See In re Kollman et al, 201 USPQ 193 (CCPA 1979). If such a reference were anticipatory, it would not be

possible to prove nonobviousness for selection inventions within a generic disclosure. Such is not the state of the law.

Further, such generic disclosure does not support application of the case law wherein anticipation can be found when one of ordinary skill in the art would "clearly envisage" a specific claimed embodiment within a genus. Such case law (e.g., In re Petering, 133 USPQ 275, 280 (CCPA 1962), and, more recently, <u>Bristol-Myers Squibb Co. v. Ben Venue</u> <u>Laboratories</u>, Inc., 58 USPQ2d 1508 (Fed. Cir. 2001)) pertains to anticipation of a species disclosed within a "small genus." Petering pertained to selection of species within a "limited class" genus of 20 compounds and Bristol-Meyers Squibb pertained to selection of one of three classes of premedicants from only a possible "few classes." Here the disclosure of 6-hydroxy-luteolin is buried within a list of 96 flavonoids. Further, Rosenbloom goes on at col. 6, lines 41-43, to list preferred flavonoids and 6-hydroxy-luteolin is not included in that list. Contrary to supporting anticipation, the facts here are analogous to the case law holding that a broad genus does not anticipate a species encompassed therein; see, e.g., Minnesota Mining & Manufacturing Co. v. Johnson & Johnson Orthopaedic, Inc., 24 USPQ2d 1321, 1332 (Fed.Cir. 1992); Ultradent Products, Inc. v. Life-like Cosmetics, Inc., 44 USPQ2d 1336 (Fed.Cir. 1997); and In re Kollman et al, 201 USPQ 193 (CCPA 1979). See also Metabolite Laboratories Inc. v. Laboratory Corporation of America Holdings, 71 USPQ2d 1081 (Fed.Cir. 2004), stating "Under [this] theory, a claim to a genus would inherently disclose all species. We find [this] argument wholly meritless."

Second, Rosenbloom fails to disclose a composition containing a compound according to applicants' formula I wherein the compound "combines anti-oxidant and UV absorption properties." See the amendment to claim 1. Rosenbloom provides no disclosure or suggestion that the flavonoid compounds, particularly 6-hydroxy-luteolin, have either anti-oxidant or UV absorption properties. To the contrary, Rosenbloom discusses the use of anti-oxidants and UV-blockers separately from the disclosure of flavonoids and does not suggest that 6-hydroxy-luteolin is either an anti-oxidant or UV-blocker.

Third, Rosenbloom fails to disclose a composition containing a compound of the formula I in an amount of from 0.01 to 20% by weight of such composition. Rosenbloom discloses the use of the flavonoids in an amount of 0.02 to 2 grams per gram of antioxidant. However, Rosenbloom does not disclose the percentage amount of the flavonoids in the

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composition as a whole. Further, the specific composition examples of Rosenbloom contain no compositions containing 6-hydroxy-luteolin. Thus, there is no specific disclosure of an embodiment which contains 0.01 to 20% by weight of 6-hydroxy-luteolin, or any other compound of applicants' formula I.

Fourth, regarding claim 9, Rosenbloom provides only a remote generic disclosure of the optional use of unspecified UV blockers. It does not appear to provide any specific embodiment of a composition containing a UV-blocker. In the absence of any specific disclosure, Rosenbloom fails to anticipate the claim reciting such.

Fifth, regarding claim 18, Rosenbloom provides no disclosure of a composition in the form of an emulsion. Rosenbloom lists several forms for its compositions but emulsions are not included. Further, all the specific embodiments of Rosenbloom are ointments.

It is additionally noted that new claims 19 and 20 provide further distinctions from Rosenbloom. New claim 20 excludes 6-hydroxy-luteolin from formula I.

For all of the above reasons, it is urged that Rosenbloom fails to provide a disclosure of an embodiment meeting all elements of the instant claims. Any difference of the prior art from the claims, even if allegedly insignificant, precludes anticipation under 35 U.S.C. §102. See, e.g., Richardson v. Suzuki Motor Co., 9 USPQ2d 1913, 1920 (Fed. Cir. 1989), stating "[e]very element of the claim must be literally present, arranged as in the claim." Thus, the rejection under 35 U.S.C. §102 should be withdrawn.

#### The Rejection of Claim 10 under 35 U.S.C. §103

The rejection of claim 10 under 35 U.S.C. §103, as being obvious over Rosenbloom (US Pat. No. 6,753,325) in view of Ley (U.S. Patent No. 6,265,611), is respectfully traversed.

Rosenbloom, and the distinctions of the claim invention therefrom, are discussed above and incorporated herein by reference. As discussed, Rosenbloom fails to disclose several elements of the claimed invention in addition to the specific nature of the UV filter recited in claim 10. Regarding the aspects of claim 1, Rosenbloom fails to teach or suggest a composition having a compound according to applicants' formula I, which has combined anti-oxidant and UV absorbing properties and in the amount recited in the claims. Rosenbloom's generic listing of 96 flavonoids fails to fairly suggest applicants' invention merely because it includes 6-hydroxy-luteolin within that list. Rosenbloom fails to direct one

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of ordinary skill in the art to make the particular selection of 6-hydroxy-luteolin from this long list. To the contrary, in its statement of preferences and in its composition examples, it directs one of ordinary skill in the art to other, distinct flavonoids. Further, Rosenbloom provides no suggestion at all of compounds of applicants' formula I which have combined "anti-oxidant and UV absorption properties." Thus, Rosenbloom provides no motivation to provide such compounds for achieving these properties.

Ley teaches the use of hydroxymandelic acid amides as antioxidants. It also teaches the optional use of UV filters and specific UV filters together with such antioxidants. While Ley may suggest that certain compounds are known UV filters, Ley fails to make up for the deficiencies of Rosenbloom to suggest the claimed invention. Ley teaches nothing regarding use of compounds of applicants' formula I and provides no suggestion that such compounds would have combined anti-oxidant and UV absorption properties.

New claim 19 is additionally distinct since the cited art provides no disclosure regarding compositions comprising a compound of applicants' formula I together with a cosmetic excipient to provide a cosmetic composition.

New claim 20 is additionally distinct since it excludes 6-hydroxy-luteolin from the compounds of formula I. Thus, the flavonoids of Rosenbloom are not even generically included in the long list any compound of formula I meeting this claim.

For the above reasons, it is urged that the combined teachings of Rosenbloom and Ley fail to suggest the compositions of the claimed invention comprising compounds of applicants' formula I having combined anti-oxidant and UV absorption properties. Thus, the rejection under 35 U.S.C. §103 should be withdrawn.

#### The Rejection of Claim 11 under 35 U.S.C. §103

The rejection of claim 11 under 35 U.S.C. §103, as being obvious over Ley in view of Rosenbloom, is respectfully traversed.

Ley and Rosenbloom are discussed above and that discussion is incorporated herein by reference.

It is alleged in the Office Action that Rosenbloom teaches that 6-hydroxy-luteolin possesses antioxidant properties. This is incorrect. Rosenbloom lists 6-hydroxy-luteolin among the flavonoids. Rosenbloom suggests that these flavonoids may have radioprotective

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effects and may have other beneficial properties such as anti-inflammatory and maintaining

structural integrity of ischemic or hypoxic tissue; see, e.g., col. 6, lines 6-12. Rosenbloom

also discloses 5 certain preferred flavonoids at col. 6, lines 41-43, and suggests these may

have other benefits, including that quercetin, particularly, may have an antioxidant effect; col.

6, lines 56-57. Rosenbloom does not disclose or suggest that all of its listed flavonoids have

an antioxidant effect and makes no suggestion that 6-hydroxy-luteolin possesses antioxidant

properties.

Thus, the sole reason alleged for combining the references is based on an erroneous

interpretation of the reference. Accordingly, no motivation for making the combination of the

reference teachings is provided on the record – nor is such motivation apparent from the

references. Thus, the rejection under 35 U.S.C. §103 should be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner

is kindly invited to contact the undersigned to discuss any unresolved matters.

No fee, other than the 1-Month Extension of Time being paid herewith, is believed to

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be due with this Amendment. However, the Commissioner is hereby authorized to charge

any additional fees associated with this response or credit any overpayment to Deposit

Account No. 13-3402.

Respectfully submitted,

/John A. Sopp/\_

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